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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,102	06/20/2000	Christopher Graham Raphael Parsons	MERZ30 / dln	6038

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,102	PARSONS ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's response/remarks filed February 25, 2005 wherein no amendment is filed. Claim 14 is cancelled previously.

Currently, claims 1-13 and 15-17 are pending in this application and examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. (WO 99/01416, of record) in view of Greenshaw A J ("*Behavioural pharmacology of 5-HT3 receptor antagonists: a critical update on therapeutic potential*", of record), and Ravelli et al. (of record) or Sullivan et al. (of record) or Wilde et al.(of record) for same reasons of record stated in the Office Action dated December 1, 2004.

Gold et al. discloses that administering the same 1-aminoalkylcyclohexanes compounds as the particular 5-HT3 receptor antagonists herein in combination with one or more pharmaceutically-acceptable diluents, excipients, or carriers to a living animal including a human (see page 29 line 26 to page 30 line 12), are useful in a pharmaceutical composition and method for treating, eliminating, and alleviating CNS

disorders (see page 3 lines 17-20) or a living animal for alleviation of a condition which is alleviated by an NMDA receptor antagonist. Gold et al. also disclose a method of manufacture of the instant claimed compounds. See abstract, pages 4-8, 10-20, and claims 1-34 of Gold et al.

Thus, Gold et al. teaches broad usefulness of the instant compounds in methods of the treatment of pathological conditions such as CNS disorders.

Note that Gold et al. discloses the effective amounts of the compound herein in the range of 20 mg to 100 mg/day or 10 mg to 250 mg/day, or 1-1000 mg/day or 50-500 mg/day (see page 29 lines 18-22, page 30 line 5-6), which are within or same as the effective amounts 1-1000 mg/day or 1-500 mg/day, indicated in Applicant's specification (see page 22 the last four lines of the specification).

Gold et al. does not expressly disclose the employment of the same active compounds of the formula herein in methods of treating of the particular disorders or conditions such as emesis, cerebellar tremor, or appetite in a living animal.

Greenshaw discloses that 5-HT3 receptor antagonists since their discovery and the subsequent identification of 5-HT3 receptors in the CNS are potentially useful in the treatment of nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, dementia and drug abuse.

Ravelli et al. teaches that vomiting, also as known emesis is a known and common disorder of the central nervous system (CNS) in a patient. See abstract and entire article.

Sullivan et al. teaches that appetite disorders are known disorders of the central nervous system (CNS) in a patient. See abstract and entire article.

Wilde et al. teaches that cerebellar tremor are known disorders of the central nervous system (CNS) in a patient. See abstract and entire article.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the same active compounds of the formula herein in methods of treating of the particular disorders or conditions such as emesis, cerebellar tremor, or appetite in a living animal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the same active compounds of the formula herein in methods of treating of the particular disorders or conditions such as emesis, cerebellar tremor, or appetite in a living animal, since the same active compounds are known to be useful in a method of treating CNS disorders broadly according to Gold et al. It is known that emesis, cerebellar tremor, or appetite is CNS-related disorders according to the prior art. It is also known that 5-HT3 receptor antagonists since their discovery and the subsequent identification of 5-HT3 receptors in the CNS are useful in the treatment of CNS disorders such as nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, dementia according to Greenshaw

Thus, the CNS disorders, taught by Gold et al. would encompass emesis, cerebellar tremor, appetite , nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, and dementia. Therefore, the patient population in Gold et al. is deemed to encompass the patient herein suffering emesis,

cerebellar tremor, appetite or inflammatory pain (migraine and irritable bowel syndrome).

Therefore, one of ordinary skill in the art would have reasonably expected that the same active compounds of the formula herein, would have beneficial therapeutic effects and usefulness in methods of the particular CNS disorder, emesis, cerebellar tremor, appetite or inflammatory pain (migraine and irritable bowel syndrome) in a patient, by administering the same effective amounts of the same compound of Gold et al.

Response to Argument

Applicant's arguments filed February 25, 2005 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action December 1, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art.

Applicant asserts that "[t]he Office sole basis for combining the Gold. et al. reference with the additionally cited references is that these additional references speak to treating CNS disorders. This simplistic rationale is not an adequate basis for combination, as the Office has provided no teaching that compounds which treat conditions susceptible to particular receptor activity are universally effective in treating conditions susceptible to disparate receptor activity. Consequently, the rejection is without basis in law or fact to make out an obviousness rejection." (see Applicant's remarks at page 3).

Contrary to Applicant's assertion, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the same active compounds of the formula herein in methods of treating of the particular disorders or conditions such as emesis, cerebellar tremor, or appetite in a living animal, since the same active compounds are known to be useful in a method of treating CNS disorders broadly according to Gold et al. It is known that emesis, cerebellar tremor, or appetite is CNS-related disorders according to the prior art.

Thus, the CNS disorders, taught by Gold et al. would encompass emesis, cerebellar tremor, appetite , nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, and dementia. Therefore, the patient population in Gold et al. is deemed to encompass the patient herein suffering emesis, cerebellar tremor, appetite or inflammatory pain (migraine and irritable bowel syndrome).

It is also known that 5-HT3 receptor antagonists since their discovery and the subsequent identification of 5-HT3 receptors in the CNS are useful in the treatment of CNS disorders such as nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, dementia according to Greenshaw. Note that the instant compounds are particular 5-HT3 receptor antagonists.

Therefore, one of ordinary skill in the art would have reasonably expected that the same active compounds of the formula herein being 5-HT3 receptor antagonists, would have beneficial therapeutic effects and usefulness in methods of the particular CNS disorder, emesis, cerebellar tremor, appetite or inflammatory pain (migraine and

irritable bowel syndrome) in a patient, by administering the same effective amounts of the same compound of Gold et al.

Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

The record contains no clear and convincing evidence of nonobviousness or unexpected results for treating the instant particular disorders over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 15-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and

7 of copending Application No. 10/288,819 now US patent 6,828,462 for the same reasons of record stated in the previous Office Action dated June 29, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same method-of-treating a living animal for alleviation of a condition treatable by a 5HT3 antagonist selected from the group consisting of anxiety disorders, depressive disorders, Schizophrenia and treatment related psychosis, drug and alcohol abuse disorders, cognitive disorders, Alzheimer's disease, Parkinson's disease, cerebellar tremor, migraine, appetite disorders, inflammatory bowel syndrome (1BS), and emesis, comprising the step of administering to the living animal an amount of the same compound, as the instant claimed method.

Thus, the patent 6,828,462 and the instant claims are deemed to substantially overlap.

Thus, the instant claims 1-13 and 15-17 are deemed to anticipate the claims 5 and 7 of the patent 6,828,462.

Response to Argument

Applicant's arguments filed February 25, 2005 with respect to the obviousness-type double patenting rejection of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant asserts that US 6,828,462 does not involve the same compounds as the instant application. Contrary to Applicant's assertion, the compound in US 6,828,462

does indeed involve the **same** compounds as the instant application, i.e., when U-V-W-X-Y-Z is **cyclohexane**, and R* is the same, so are the other substituens. Thus, the compounds of formula I in claim 7 are deemed to encompass the instant compounds.

Therefor, this obviousness-type double patenting rejection is maintained.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
May 25, 2005